

**REMARKS**

Applicants have reviewed and considered the non-final Office Action mailed on May 13, 2008, and the references cited therewith. Claims 1-20 are pending in the present application. Claims 11-20 have been added. Support for the claim amendments and new claims can be found in the claims as originally filed, and in the Applicants' patent application in paragraph 26. Reconsideration and allowance of the claims are respectfully requested in view of the following remarks.

**Claim Rejection – 35 U.S.C. § 103; Claims 1-3, 5, 6, and 10**

The Examiner rejects claims 1-3, 5, 6, and 10 as obvious over International Publication Number WO 00/59424 A1 (hereinafter "Johnson") in view of U.S. Patent 5,039,491 (hereinafter "Saaski"). This rejection is respectfully traversed.

The Examiner bears the burden of establishing a *prima facie* case of obviousness based on prior art when rejecting claims under 35 U.S.C. § 103. *In re Fritch*, 972 F.2d 1260, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992). Additionally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Therefore, the Examiner fails to state a *prima facie* obviousness rejection if the proposed combination does not teach or suggest all of the features of the claimed invention.

**A. Claims 1-3 and 5**

Johnson and Saaski fail to teach or suggest all of the features of claim 1, from which claims 2, 3, and 5 depend. With respect to claim 1, the Examiner states that:

With respect to claim 1: Johnson teaches a negative pressure therapy device, comprising a screen means in the form of a highly reticulated open-cell foam pad 11 for placement within a wound bed 12 (Page 3, lines 32-34, Page 4, lines 14-16), a sealing means in the form of wound drape 13 adhered over said screen means 11 and wound bed 12 (Page 3, lines 32-34) via at least peripheral coverage of the drape 13 with adhesive (Page 4, lines 21-23), and a vacuum source fluidically communicating with said screen means 11 via material hose 14.

Johnson does not teach a fluid compositional sensing device interposed between said screen means 11 and said vacuum source. Saaski teaches an optical oxygen sensor containing an indicator whose change in absorption is a function of concentration of oxygen in a sample, e.g. blood. Saaski teaches that sensors for determining blood oxygen levels are well-known in the art and can measure blood oxygen by bringing the blood to sensors outside the body, e.g. via vacuum flow such as is taught by Johnson, and teaches that this pO<sub>2</sub> measurement is an indicator of cardiovascular function of the patient, which impacts the condition of a wound site and healing time of a wound. Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Johnson so as to include an oxygen sensor for measuring oxygen concentration of the blood conveyed via vacuum flow as taught by Saaski with a reasonable expectation of success to provide an indication of a patient's cardiovascular health which impacts conditions at a wound site as well as healing of the wound. The concentration of oxygen in a patient's blood at a wound site is considered herein to be a fluid compositional characteristic of unfiltered wound fluid from the wound bed, as the unfiltered fluid is largely comprised of blood and oxygen is part of the fluid's composition. The combined teaching of Johnson and Saaski thus renders the limitation "wherein the fluid compositional sensing device senses compositional characteristics of unfiltered wound fluid from the wound bed" obvious. (Office Action dated May 13, 2008, page 3).

This rejection is respectfully traversed. In particular, neither Johnson nor Saaski teaches or suggests at least a fluid compositional sensing device interposed between said dressing and said vacuum source. As an initial matter, the Examiner admits that "Johnson does not teach a fluid compositional sensing device interposed between said screen means 11 and said vacuum source." (Office Action dated May 13, 2008, page 3). Johnson also does not suggest this claimed feature.

However, the Examiner cites Saaski against this claimed feature. Saaski discloses an electro-optical sensor for measuring the concentration of oxygen in a substance based upon changes in the optical absorption characteristics of a chemical indicator when exposed to oxygen. The sensing device of Saaski is disclosed in the following portion of Saaski:

A sensor of the present invention includes an indicator chamber containing an indicator that receives radiation having predetermined color characteristics. An aperture opening into the indicator chamber allows the substance being analyzed to enter the indicator chamber.

The indicator has radiation-absorption characteristics that change when the indicator is exposed to oxygen. More specifically, the indicator chosen is one in which radiation absorption/transmission characteristics at a first wavelength change during or after being illuminated with light at a second wavelength. The rate at which the absorption/transmission characteristics change is a function of the concentration of oxygen to which the indicator is exposed. An example of such an indicator is one of the class of compounds called "viologens." A light-measuring unit is provided for receiving reflected radiation and generating a signal indicative of the concentration of oxygen in the substance being analyzed. In operation, the optical measurement system first sends a pulse of light at the second wavelength to the indicator in the sensor. The absorption/transmission of the indicator for the first wavelength waveband of light then markedly increases. The rate at which the absorption/transmission characteristics change for the light at the first wavelength is a function of the concentration of oxygen to which the indicator is exposed. (Saaski, column 2, lines 7-33).

The cited portion discloses that Saaski's sensor includes an indicator chamber that contains an indicator that receives radiation having predetermined color characteristics. The location of the sensor is not disclosed. Claim 1, on the other hand, recites a fluid compositional sensing device interposed between said dressing and said vacuum source. Saaski differs from the claimed feature because neither the cited portion nor any other portion of Saaski teaches or suggests any dressing or vacuum source, let alone that the disclosed oxygen sensor is between a dressing and a vacuum source. Thus, Johnson and Saaski, alone or in combination, fail to teach or suggest all of the features of claim 1, or any claims dependent therefrom.

#### B. Claims 6 and 10

Johnson and Saaski fail to teach or suggest all of the features of claim 6, from which claim 10 depends. With respect to claim 6, the Examiner states that:

With respect to claim 6: Johnson teaches a negative pressure therapy device, comprising a screen means in the form of a highly reticulated open-cell foam pad 11 for placement within a wound bed 12 (Page 3, lines 32-34, Page 4, lines 14-16), a sealing means in the form of wound drape 13 adhered over said screen means 11 and wound bed 12 (Page 3, lines 32-34) via at least peripheral coverage of the drape 13 with adhesive (Page 4, lines 21-23), and a vacuum source

fluidically communicating with said screen means 11 via material hose 14. Johnson teaches a collection canister interposed between said screen means and said vacuum source. (Page 4, lines 18-21)

Johnson does not teach a fluid compositional sensing device interposed between said screen means 11 and said vacuum source. Saaski teaches an optical oxygen sensor containing an indicator whose change in absorption is a function of concentration of oxygen in a sample, e.g. blood. Saaski teaches that sensors for determining blood oxygen levels are well-known in the art and can measure blood oxygen by bringing the blood to sensors outside the body, e.g. via vacuum flow such as is taught by Johnson, and teaches that this  $pO_2$  measurement is an indicator of cardiovascular function of the patient, which impacts the condition of a wound site and healing time of a wound. Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Johnson so as to include an oxygen sensor for measuring oxygen concentration of the blood conveyed via vacuum flow as taught by Saaski with a reasonable expectation of success to provide an indication of a patient's cardiovascular health which impacts conditions at a wound site as well as healing of the wound. The concentration of oxygen in a patient's blood at a wound site is considered herein to be a fluid compositional characteristic of unfiltered wound fluid from the wound bed, as the unfiltered fluid is largely comprised of blood and oxygen is part of the fluid's composition. The combined teaching of Johnson and Saaski thus renders the limitation "wherein the fluid compositional sensing device senses compositional characteristics of unfiltered wound fluid from the wound bed" obvious.

With regard to the limitation "for detecting infection", the device of the combined teaching of Johnson and Saaski meets all of the limitations as to a fluid compositional sensing device and thus the instant fluid compositional sensing device is fully capable of detecting infection. With regard to the limitation "said compositional characteristics indicative of said infection within the wound", the instant compositional characteristic, i.e. concentration of oxygen in blood that is within the wound bed fluid, is indicative of infection within the wound inasmuch as insufficient oxygen causes, and is a sign of, infection in a wound bed. (Office Action dated May 13, 2008, pages 5 and 6).

This rejection is respectfully traversed. In particular, neither Johnson nor Saaski teaches or suggests at least (1) a fluid compositional sensing device for detecting infection, or (2) the feature wherein the fluid compositional sensing device senses compositional characteristics of unfiltered wound fluid from the wound bed, said compositional characteristics indicative of said infection within the wound.

B.I. Neither Johnson nor Saaski teaches or suggests a fluid compositional sensing device for detecting infection

Neither Johnson nor Saaski teaches or suggests a fluid compositional sensing device for detecting infection. Nonetheless, the Examiner cites Saaski against this claimed feature. As shown in the portion of Saaski reproduced in the previous section, Saaski discloses a sensor for measuring the concentration of oxygen in a substance. Saaski differs from the claimed feature because Saaski nowhere addresses the issue of infection, let alone teaches or suggests that the disclosed sensor is capable of detecting infection.

Furthermore, Saaski explicitly discloses that the measurement of oxygen is regarded as a critical measure “in the clinical assessment of pulmonary and cardiovascular function.” (Saaski, column 1, lines 16-18). Saaski nowhere discloses that the sensor disclosed therein measures oxygen to detect an infection. Thus, Saaski fails to teach or suggest this claimed feature.

In addition, Johnson discloses a vacuum assisted closure system with provision for the introduction of an agent. Johnson nowhere teaches or suggests a fluid compositional sensing device for detecting infection, and the Examiner fails to assert otherwise. Thus, Johnson and Saaski, alone or in combination, fail to teach or suggest all of the features of claim 6, or any claims dependent therefrom.

B.II. Neither Johnson nor Saaski teaches or suggests the feature wherein the fluid compositional sensing device senses compositional characteristics of unfiltered wound fluid from the wound bed, said compositional characteristics indicative of said infection within the wound

Neither Johnson nor Saaski teaches or suggests the feature wherein the fluid compositional sensing device senses compositional characteristics of unfiltered wound fluid from the wound bed, said compositional characteristics indicative of said infection within the wound. As shown in the portion of Saaski reproduced in the previous section, Saaski discloses a sensor for measuring the concentration of oxygen in a substance. Saaski differs from the claimed feature because Saaski nowhere addresses the issue of

infection, let alone teaches or suggests that the composition of oxygen detected by Saaski's sensor is indicative of an infection within a wound.

Furthermore, Saaski explicitly discloses that the measurement of oxygen is regarded as a critical measure "in the clinical assessment of pulmonary and cardiovascular function." (Saaski, column 1, lines 16-18). Saaski nowhere discloses that the composition of oxygen measured by the sensor disclosed therein is indicative of an infection within a wound. Thus, Saaski fails to teach or suggest this claimed feature.

In addition, Johnson discloses a vacuum assisted closure system with provision for the introduction of an agent. Johnson nowhere teaches or suggests the feature wherein the fluid compositional sensing device senses compositional characteristics of unfiltered wound fluid from the wound bed, said compositional characteristics indicative of said infection within the wound. Thus, Johnson and Saaski, alone or in combination, fail to teach or suggest all of the features of claim 6, or any claims dependent therefrom.

Claim Rejection – 35 U.S.C. § 103; Claim 4

The Examiner rejects claim 4 as obvious over Johnson in view of Saaski, and further in view of U.S. Patent 6,017,440 (hereinafter "Lewis"). This rejection is respectfully traversed.

The rejection of claim 4 relies on the false premise that Johnson and Saaski teach or suggest all of the features of claim 1, from which claim 4 depends. However, as shown above, Johnson and Saaski fail to teach or suggest at least a fluid compositional sensing device interposed between said dressing and said vacuum source. Johnson and Saaski's deficiencies with respect to claim 4 are not cured by Lewis, and the Examiner does not assert otherwise. Therefore, Johnson, Saaski, and Lewis, alone or in combination, fail to teach or suggest all of the features of claim 4.

Claim Rejection – 35 U.S.C. § 103; Claim 7

The Examiner rejects claim 7 as obvious over Johnson in view of Saaski, and further in view of U.S. Patent 5,855,570 (hereinafter “Scherson”). This rejection is respectfully traversed.

The rejection of claim 7 relies on the false premise that Johnson and Saaski teach or suggest all of the features of claim 6, from which claim 7 depends. However, as shown above, Johnson and Saaski fail to teach or suggest at least (1) a fluid compositional sensing device for detecting infection, or (2) wherein the fluid compositional sensing device senses compositional characteristics of unfiltered wound fluid from the wound bed, said compositional characteristics indicative of said infection within the wound. Johnson and Saaski’s deficiencies with respect to claim 7 are not cured by Scherson, and the Examiner does not assert otherwise. Therefore, Johnson, Saaski, and Scherson, alone or in combination, fail to teach or suggest all of the features of claim 7.

Claim Rejection – 35 U.S.C. § 103; Claim 8

The Examiner rejects claim 8 as obvious over Johnson in view of Saaski, and further in view of U.S. Patent 6,398,767 (hereinafter “Fleischmann ”). This rejection is respectfully traversed.

The rejection of claim 8 relies on the false premise that Johnson and Saaski teach or suggest all of the features of claim 6, from which claim 8 depends. However, as shown above, Johnson and Saaski fail to teach or suggest at least (1) a fluid compositional sensing device for detecting infection, or (2) wherein the fluid compositional sensing device senses compositional characteristics of unfiltered wound fluid from the wound bed, said compositional characteristics indicative of said infection within the wound. Johnson and Saaski’s deficiencies with respect to claim 8 are not cured by Fleischmann, and the Examiner does not assert otherwise. Therefore, Johnson, Saaski, and Fleischmann, alone or in combination, fail to teach or suggest all of the features of claim 8.

Claim Rejection – 35 U.S.C. § 103; Claim 9

The Examiner rejects claim 9 as obvious over Johnson in view of Saaski, and further in view of U.S. Patent 4,955,391 (hereinafter “Parker”). This rejection is respectfully traversed.

The rejection of claim 9 relies on the false premise that Johnson and Saaski teach or suggest all of the features of claim 6, from which claim 9 depends. However, as shown above, Johnson and Saaski fail to teach or suggest at least (1) a fluid compositional sensing device for detecting infection, or (2) wherein the fluid compositional sensing device senses compositional characteristics of unfiltered wound fluid from the wound bed, said compositional characteristics indicative of said infection within the wound. Johnson and Saaski’s deficiencies with respect to claim 9 are not cured by Parker, and the Examiner does not assert otherwise. Therefore, Johnson, Saaski, and Parker, alone or in combination, fail to teach or suggest all of the features of claim 9.

New Claims 11-20

Applicants have added new claims 11-20. No anticipation or *prima facie* obviousness rejection may be stated against new claims 11-20. Additionally, new claims 11-20 claim additional features and combinations of features not taught or suggested by the cited references.

## CONCLUSION

If a Petition for Extension of Time under 37 C.F.R. 1.136(a) is required, the petition is herewith made. The Commissioner is authorized to charge any fees that may be required, or credit any overpayment made with this Office Action, to Deposit Account Number 19-3140.

In light of all the foregoing, believing that all things raised in the Office Action have been addressed, Applicant respectfully requests reconsideration of the prior rejections and objections, as well as allowance of the claims and passage of the application to issue. If the Examiner would care to discuss any remaining matters by phone, Applicant invites the Examiner to contact the undersigned at (214) 259-0900.

Respectfully submitted,

  
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